DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2008

Paieon, Inc.
% Ravit Barkama, M.D.
Medical Director
Paieon Medical Ltd.
747 Third Ave., 4th Floor
NEW YORK NY 10017-2803

Re: K073328
Trade/Device Name: CardiOp-B System (version 2.1 with LVA)
Regulation Number: 21 CFR 892.1600
Regulation Name: Angiographic x-ray system
Regulatory Class: II
Product Code: IZI
Dated: August 21, 2008
Received: August 27, 2008

Dear Dr. Barkama:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

Device Name: **The CardiOp-B System**

Indications for Use:

The CardiOp-B System is a software system that assists in the evaluation of coronary lesions by enabling the creation of 3D images of coronary vessel segments based on two to three 2D angiography images obtained from single plane angiography. CardiOp-B provides quantitative information regarding the calculated dimensions of arterial segments based on the 3D image. CardiOp-B can also perform quantitative analysis of the left ventricle based on left ventricular angiograms. CardiOp-B is intended for use in real-time in the catheterization lab and off-line for post-procedural analysis. It is intended for use by clinicians, technicians and research personnel.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073328

(Posted November 13, 2003)

510(k) SUMMARY—CardiOp-B System

Submitter Name:	Paieon Inc.
Submitter Address:	747 Third Ave., 4th floor New York, NY 10017-2803
Contact Person:	Ravit Barkama, MD
Phone Number:	+972 3 915 0000
Fax Number:	+972 3 901 2324
Date Prepared:	Nov 22, 2007
Device Trade Name:	The CardiOp-B System
Device Common Name:	Cardiovascular Angiography Analysis System
Classification Name:	Angiographic x-ray system
Predicate Devices:	CardiOp-B cleared for marketing under K072591, QLV-CMS cleared under K993765 and CAAS Software package cleared under K052988
Device Description:	The CardiOp-B System is an image acquisition and processing software system designed as an add-on to conventional X-ray angiography systems. The CardiOp-B system improves the output of coronary angiography by presenting a three-dimensional reconstruction of the stenosed vessel as well as quantitative cross-section information. The LVA (Left Ventricular Analysis) package is an addition to the CardiOp-B System which is the subject of this Traditional 510(K).

Intended Use:	The CardiOp-B System is a software system that assists in the evaluation of coronary lesions by enabling the creation of 3D images of coronary vessel segments based on two to three 2D angiography images obtained from single plane angiography. CardiOp-B provides quantitative information regarding the calculated dimensions of arterial segments based on the 3D image. CardiOp-B can also perform quantitative analysis of the left ventricle based on left ventricular angiograms. CardiOp-B is intended for use in real-time in the catheterization lab and off-line for post-procedural analysis. It is intended for use by clinicians, technicians and research personnel.
Performance Standards:	None
Performance Data:	Testing included software validation and performance evaluation. Performance testing was performed to evaluate the modifications to the CardiOp-B system and produced accuracy and precision results within the predetermined specifications and comparable to results obtained by the marketed predicate devices.
Substantial Equivalence:	The CardiOp-B system with the LVA package is similar in intended use and technology (overall design, principle of action, mode of operation, performance characteristics, etc.) to the cleared predicate devices.
Conclusion:	The testing reported in this 510(K) establishes the modified CardiOp-B is substantially equivalent to the predicate devices and is safe and effective for its intended use.